REMARKS

I. PRELIMINARY REMARKS

Claim 46 has been canceled. No claims have been added. Claim 44 has been amended. Claims 44, 47-50 and 148-154 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. REJECTION UNDER SECTION 112

A. The Rejection

Claims 44, 46-50 and 148-154 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the invention. As claim 46 has been canceled, the rejection thereof under 35 U.S.C. § 112 has been rendered moot. The rejection of the remaining claims under 35 U.S.C. § 112 is respectfully traversed. Reconsideration thereof is respectfully requested.

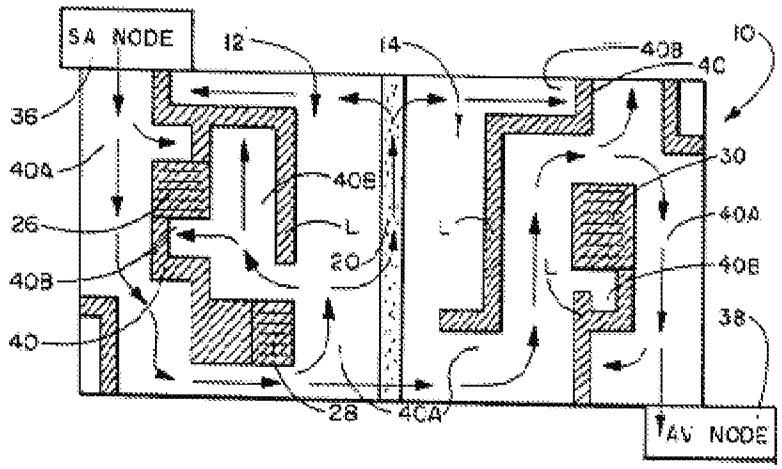
B. Discussion

Independent claims 44, 148, 150 and 153 call for various combinations of elements that relate to the formation of a lesion in, or the transmission of energy to, a circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium. Veins that carry blood to an atrium include the superior vena cava (SVC) and the inferior vena cava (IVC) in the right atrium, and the pulmonary veins (PVs) in the left atrium. The Office Action has apparently taken the position that there is no support in the present application, as filed, for the formation of an individual lesion around the SVC or the formation of an

individual lesion around the IVC or the formation of an individual lesions around one of the PVs. Applicant respectfully submits that the position taken in the Office Action is incorrect.

By way of background, the present application discloses a wide variety of apparatus that may be use to, for example, form some or all of the lesions in the so-called "maze pattern." The maze pattern of lesions is illustrated in Figure 2 of the present application, which is reproduced below. Referring first to the right atrium 12, one lesion is positioned around the SVC 26 and another lesion is positioned around the IVC 28. The lesions around the SVC 26 and the IVC 28 are connected by other lesions. [Note the horizontally and vertically extending lesions that are located between the lesions around SVC 26 and the IVC 28.] Turning to the left atrium 14, it is not entirely clear whether the shaded rectangular area is being used to show individual lesions around each of the pulmonary veins, or a single lesion around all of the pulmonary veins.

FIG. 2



Turning to the structures disclosed in the present application for forming lesions around the SVC 26, the IVC 28 and the PVs 30, and as discussed in the paragraph quoted below, the hoop 162 illustrated in Figure 13 is one example of a structure that may be used to form all or part of a maze pattern.

> The alternative element 42(6) differs from the previously described multiple spline baskets 92(1) to (5) in that it forms a single hoop 162. The hoop 162 allows the physician to form, as part of ***the lesion pattern***, lesion**s** that substantially encircle the orifice**s** of the SVC 26 and the IVC 28 in the right atrium 12 and the PV's 30 in the left atrium 14 (see Fig. 1).

> Furthermore, by using ***one or more hoops 162 in succession***, the physician can eventually form an entire lesion pattern.

[Spec. at page 46, lines 23-32, emphsasis added.] Applicant respectfully submits that, based on Figure 2, the paragraph quoted above, and/or general knowledge concerning the heart and maze procedures, one of skill in the art would understand the following:

1. The SVC, the IVC and PVs are all veins that carry blood to an atrium.
2. The lesion pattern referred to in the above-quoted paragraph is the maze lesion pattern illustrated in Figure 2.
3. The maze lesion pattern illustrated in Figure 2 includes separate lesions around the SVC and the IVC and, accordingly, there is no reasonable interpretation of the phrase "lesion**s** that substantially encircle the orifice**s** of the SVC 26 and the IVC 28" that would include "a single lesion that encircles both the IVC and the SVC" as was asserted in the Office Action.
4. The maze procedure lesion pattern illustrated in Figure 2 is unclear with respect to the lesion configuration associated with the PVs and, accordingly, it is at least as likely as not that "lesion**s** that substantially encircle the orifice**s** of the SVC 26 and the IVC 28 in the right atrium 12 and the PV's 30" would be interpreted as referring to individual lesions around the PVs.
5. The reference to "one or more hoops 162 in succession" is a reference to one or more hoops of different sizes that may be used to form different portions of the maze lesion pattern. This, in turn, supports the proposition that hoops which are sized to form individual lesion around the SVC, IVC and PVs are described in the specification.

Accordingly, applicant respectfully submits that the specification, as filed, provides support for the concept of forming an individual lesion around the SVC, forming an individual lesion around the IVC, and forming individual lesions around each of the PVs.

It should also be noted that even if the Examiner disagrees with applicant's arguments concerning the PV's, the claims are ***generic to all veins that carry blood to an atrium***. Applicant respectfully submits that the generic claims are clearly supported by the two other examples of the formation of a lesion around a vein that carries blood to an atrium, i.e. the lesion around the SVC and the lesion around the IVC.

In view of the forgoing, applicant respectfully submits that the rejection of claims 44, 47-50 and 148-154 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

III. REJECTION UNDER SECTION 102

A. The Rejection

Claims 44, 46-50 and 148-154 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,263,493 to Avitall ("the Avitall '493 patent"). As claim 46 has been canceled, the rejection thereof under 35 U.S.C. § 102 has been rendered moot. The rejection of the remaining claims under 35 U.S.C. § 102 is respectfully traversed. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 44 and 47-50

Independent claim 44 calls for an ablation device comprising "a member defining an expanded size and shape that corresponds to a circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium" and "an ablation element associated with the member and adapted to form a ***continuous circumferential lesion*** in the circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium." The respective combinations defined by claims 47-50 include, *inter alia*, the elements recited in claim 44.

The Avitall '493 patent fails to teach or suggest the claimed combinations. For example, the Avitall loop structures have expanded sizes and shapes that correspond to the tricuspid annulus, not to an orifice of a vein that carries blood to an atrium. [See, e.g., column 3, lines 5-7, 20-25, 39-40 and 53-56; column 4, lines 21-25; column 5, lines 14-16; and column 7, lines 17-40.] The Office Action has not shown that a size and shape that corresponds to the tricuspid annulus also "corresponds to a circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium." Instead, the Office Action appears to have argued that because the Avitall loop structures are larger than a single pulmonary vein, the Avitall loop structures have sizes and shapes that

"correspond to" that of a vein that carries blood to the atrium. Applicant respectfully submits that this is an unreasonable interpretation of the claim.

The Avitall '493 patent also fails to teach or suggest that the loop structures disclosed therein are adapted to form a ***continuous circumferential lesion***. Instead, the Avitall '493 patent indicates that the devices may be used to map a circumferential region of tissue and, based on the results of the mapping, "ablate the desired tissue using the same mapping ***electrode*** in the array that is positioned on or near the ***site*** that should be ablated," create a lesion "in the area from which the arrhythmia originates," ablate "the most appropriate location," or ablate "the most desirable location". [Column 1, lines 21-25; column 2, lines 64-66; column 3, lines 4-9; and column 3, lines 28-33.] Additionally, and even assuming for the sake of argument that the device illustrated in Figures 6A-6C could form continuous lesions between the electrodes on the right and left sides of the loop (as oriented in Figure 6A), the spacing between the electrodes at the distal and proximal ends of the loop would appear to prevent the formation of a continuous circumferential lesion. The device illustrated in Figure 1A would, at a minimum, suffer from the same shortcoming.

As the Avitall '493 patent fails to teach or suggest each and every element of the combination recited in independent claim 44, applicant respectfully submits that claims 44 and 47-50 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

C. Discussion Concerning Claims 148-154

Independent claims 148, 150 and 153 includes means-plus-function elements. The MPEP requires a ***two-part analysis*** of means-plus-function elements. ***First***, "the application of a prior art reference to a means or step plus function limitation ***requires*** that the prior art element ***perform the identical function*** specified in the claim." [MPEP § 2182, emphasis added.] ***Second***, "***if a prior art reference teaches identity of function*** to that specified in a claim, ***then*** under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as

corresponding to the claimed means or step plus function." [Id., emphasis added.] The outstanding Office Action did not perform the first part of the claim interpretation analysis mandated by the MPEP and, instead, simply focused on the second part. As such, the arguments below focus primarily on the first part.

Independent claim 148 is directed to a catheter that comprises "a catheter body" and "***means***, associated with the catheter body, ***for forming a lesion in at least a substantial portion of a circumferential region of tissue associated with an orifice of a vein that carries blood to an atrium***." The Avitall '493 patent fails to teach or suggest that the loops disclosed therein perform, or are even capable of performing, the function set forth in the means-plus-function element. The Avitall '493 patent discloses the formation of a lesion at a site where an arrhythmia originates based on mapping results. [Column 1, lines 21-25; column 2, lines 64-66; column 3, lines 4-9; and column 3, lines 28-33.] Moreover, with respect to the atrium, the only specific reference to the ablation of atrial tissue is the generic reference to the ablation of "the arrhythmogenic site within the atria" in the background portion of the Avitall '493 patent. [Column 2, lines 58-62.] It should also be noted that column 4, lines 20-30 of the Avitall '493 patent, which was cited in the Office Action, merely refers to the mapping of "atrial and ventricular electrical activity ***at the posterior and anterior aspect of the tricuspid ring***," and does not refer to "tissue associated with an orifice of a vein that carries blood to an atrium."

Independent claim 150 is directed to a catheter that comprises "a catheter body including at least one energy transmission line" and "***means***, operably connected to the at least one energy transmission line, ***for simultaneously coupling a continuous circumferential region of tissue that surrounds an orifice of a vein that carries blood to an atrium to energy from the at least one energy transmission line***." The Avitall '493 patent fails to teach or suggest, for example, that the loops disclosed therein perform the function set forth in the means-plus-function element. As alluded to above, the functionality disclosed in the Avitall '493 patent is coupling a particular arrhythmogenic site, not a "continuous circumferential region of tissue that surrounds an orifice of a vein that carries blood to an atrium," to an energy transmission line.

Independent claim 153 is directed to a catheter that comprises "a catheter body" and "***means***, associated with the catheter body, ***for expanding within an atrium, contacting a circumferential region of tissue that surrounds an orifice of a vein that carries blood to the atrium, and forming a continuous lesion in the circumferential region of tissue***." The Avitall '493 patent fails to teach or suggest, for example, that the loops disclosed therein perform the function set forth in the means-plus-function element. There is simply no disclosure concerning the contacting of tissue around "an orifice of a vein that carries blood to the atrium" or the formation of "a continuous lesion in the circumferential region of tissue."

As the Avitall '493 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 148, 150 and 153, applicant respectfully submits that claims 148-154 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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